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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,329	03/01/2004	Kevin T. Foley	4002-3486/PC746.02	9011

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EXAMINER

SWEET, THOMAS

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/790,329

Applicant(s)

FOLEY, KEVIN T.

Examiner

Thomas J Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44-47, 50-58 and 60-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 44, 47 and 60-80 is/are rejected.
- 7) ☒ Claim(s) 45, 46 and 50-58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claim 47 and 60-80 have been considered but are moot in view of the new ground(s) of rejection. The "if then" language per se wasn't the problem with the claims being indefinite. The method has a gapping hole in it which needed an "else" to keep it bounded and prevent the method from spiraling out of on control (please refer to the new 35 U.S.C. 101 and 35 U.S.C. 112 rejections of these claims).

Applicant's arguments filed 3/9/2005 have been fully considered but they are not persuasive. In the broadest reasonable interpretation of method claims any reference which meets all the claimed steps reads on the claim even if additional steps are present. Ralph et al includes the additional step of inserting the correct size trial implant and removing it. That implant need not be consisted one of the "number of implants".

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 47 and 60-80 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. If the first implant is the correct size, the method requires inserting a second implant of the correct size selected from a group of other implant not of the right size.

### ***Claim Rejections - 35 USC § 112***

Art Unit: 3738

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47 and 60-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The method as claimed is not the method as disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47, 60-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claimed procedure is open ended and therefore the scope of the claims can not be discerned (see the 35 U.S.C. 101 rejection).

Claims 47, 60-80 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: leaving the first implant in place when it is the correct restorative disc height.

***Claim Rejections - 35 USC § 102***

Art Unit: 3738

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44, 47, 60-66 and 70-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Ralph et al. Ralph et al discloses a method (abstract) for inserting an intervertebral implant, comprising: accessing a collapsed spinal disc space (uni-portal, Col 3, lines 8-28); sequentially inserting and removing a number of implants (i.e. one of which is the porous spacer and not the trial implant) into the collapsed spinal disc space (abstract), each of said implants providing a different restored disc space height when inserted in the disc space, the spinal disc space at least partially collapsing when the inserted implant is removed therefrom (inherent); and leaving in the spinal disc space the implant (inserting the porous spacer from the last line of the abstract meets this step under broadest reasonable interpretation since it is the same size as the appropriate trial implant) from the number of implants providing a restored disc space height corresponding to a desired disc space height to post-operatively maintain the desired disc space height.

In the broadest reasonable interpretation of the claim 47, Ralph et al meets this method since the procedure is open ended when the first implant is the correct height. When the first trial implant of Ralph et al is the correct height it would be replaced with the second porous implant from a number (just one) of implants (not counting the first implant as one of the

Art Unit: 3738

number) also of the correct height and would be left inserted to post-operatively maintain the spacing.

With regard to claims 61 and 70-72, for an appropriate disc height of 3-6 mm (3-4 for flat implants and 5-6 for angular implants of Ralph et al) as determined by surgical experience, when first trial implant of Ralph et al is the correct height it would be replaced with the second porous implant from a number (just one) of implants (not counting the first implant as one of the number) also of the correct height and would be left inserted to post-operatively maintain the spacing and would have a nose portion of 3-4 mm.

With regard to claims 62-65 and 70-76, the rounded and angular embodiment of Ralph et al (fig. 4d).

With regard to claims 67 and 78, See figure 5b and the corresponding text in Columns 14-15.

#### ***Allowable Subject Matter***

Claims 45-46 and 50-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs

  
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